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# TRANSMITTAL FORM

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| Application Number | 09/990,611 |
| Filing Date | November 21, 2001 |
| First Named Inventor | Lorraine Faxon Meisner |
| Art Unit | 1616 |
| Examiner Name | F. Choi |
| Attorney Docket Number | 41758/P001P1C2X1 |

Total Number of Pages in This Submission

## ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
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  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  Acknowledgment Postcard

**Remarks**

The attached Amended Appeal Brief is filed in triplicate.

Applicant claims small entity status. A check in the amount of $250.00 was paid in the original filng of the Appeal Brief on December 2, 2005. Any excess of insuffiency should be credited or debited to Deposit Account No. 23-2426.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|---|---|---|---|
| Firm Name | Winstead Sechrest & Minick, P.C. | | |
| Signature | Carol M. Nielsen | | |
| Printed name | Carol M. Nielsen | | |
| Date | January 5, 2006 | Reg. No. | 37,676 |

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

| | |
|---|---|
| **Group Art Unit:** | **1616** |
| **Examiner:** | **F. Choi** |
| **Applicants:** | **Meisner, Lorraine Faxon** |
| **Application Number:** | **09/990,611** |
| **Filed:** | **November 21, 2001** |
| **For:** | **ASCORBIC ACID COMPOSITION AND METHOD FOR TREATMENT OF AGING OR DAMAGED SKIN** |

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## AMENDED APPEAL BRIEF

Appellant appeals from the rejections of claims 1, 3-8, 10-12, 15-18, 21, 23-25 dated May 9, 2005 in the above-identified patent application.

The fee of $250 as required under § 41.20 (2) was paid in the original filing of the brief on December 2, 2005.

## Real Parties In Interest

The real party in interest is Bioderm, Inc., the assignee of the entire right and interest in the present application.

## Related Appeals and Interferences

There are no other related appeals and/or interferences pending.

## Status of Claims

The application was filed with original claims 1-26. Claims 1, 3-8, 10-12, 15-18, 21, 23-25 are pending in the application. Claims 2, 9, 13, 14, 19-20, 22 and 26 are cancelled. claims 1, 3-8, 10-12, 15-18, 21, 23-25 are rejected. Claims 2, 9, 13, 14, 19-20, 22 and 26 are being appealed.

## Status of Amendments

An amendment to the claims was filed on December 1, 2005 after Office Action Mailed May 9, 2005 and before the filing of this brief. In amendment, cancellation of claims 13, 14, 22 and 26 is requested.

## Summary of Claimed Subject Matter

Claim 1, upon which claims 3 through 17 ultimately depend, is a topical composition having a pH of 3.5 to 4.1, at least 5.0% (w/v) ascorbic acid, water and a non-toxic zinc salt. *See,* U.S. Pat. App. Ser. No. 09/990,611 ("*Application*") at 5, ls. 8-11; p. 6, ls. 22-29; p. 8, ls. 3-8; p. 9, ls. 13-20. The ascorbic acid may or may not be pretreated. At this pH range and having a relatively high weight percent volume of ascorbic acid, the subject topical composition is surprising stable, causing little or no irritating effects to the skin. *Id.* at 6, ls. 12,1-4, 22-29. The topical composition may also include an anti-inflammatory compound and/or a tyrosine

compound. *See, e.g.,* Claims 4-8. A pharmaceutically acceptable carrier may also be present in the subject composition. *Id.* at 9, line 21 through page 10, at line 8. Furthermore, the topical composition of the present invention may be an aqueous solution or blended into a tissue compatible vehicle such as a serum, a lotion, an ointment, a cream, or a gel. *Id.* at 10, ls. 26-31.

Claim 18, upon which claim 21 and claims 23 through 25 depend, is topical composition having a pH of 3.5 to 4.1 comprising an aqueous solution having at least 5.0% (w/v) pretreated ascorbic acid, water and a non-toxic zinc salt.

**Grounds of Rejection To Be Reviewed on Appeal**

Whether claims 18, 21, and 23-25 are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Whether claims 18, 21, and 23-25 are unpatentable under 35 U.S.C. § 112, second paragraph, for being incomplete for omitting essential elements.

Whether claims 1, 3-8, 10-12, 15-18, 21, 23-25 are unpatentable under 35 U.S.C. § 103 (a) as being unpatentable over *Schinitsky et al.*, U.S. Pat. No. 4,938,969 in view of *Murad,* U.S. Pat. No. 5,804,594, *Herstein,* U.S. Pat. No. 5,902,591 and *Bassford et al.*, U.S. Pat. No. 2,517,276.

Whether claims 1, 3-8, 10-12, 15-18, 21, 23-25 are unpatentable under 35 U.S.C. § 103 (a) as being unpatentable over *Schinitsky et al.*, US Pat. No. 4,938,969 in view of *Murad*, US Pat. No. 5,804,594, *Darr et al.*, US Pat. No. 5,140,043 and *Bassford et al.*, US Pat. No. 2,517,276.

**Grouping of Claims**

The claims do not stand or fall together. As discussed in more detail below, claim 18 and dependent claims 21, and 23-25 require ascorbic acid to be pretreated. However, claim 1 is not

limited to a composition containing pretreated ascorbic acid. Pretreatment of the ascorbic acid has been shown to further increase the stability of the claimed topical composition. *Application* at 5, ls. 3-8; p. 6, ls. 30-32; p. 7, ls. 27 to 30. When the ascorbic acid is pretreated, the topical composition of the subject invention has additional benefits in that it does not expand, explode, or discolor as a result of heat, changes in atmospheric pressure, or improper storage. *Id.* at 5, ls. 3-8. Pretreatment of ascorbic acid also reduces potential skin irritation. Pretreatment of the ascorbic acid is an additional limitation clearly not taught or suggested by the prior art. Therefore, the claims on appeal do not stand or fall together.

## Argument

### I. Rejection of the Claims under 35 U.S.C. § 112, First Paragraph, for Lack of Enablement is Improper.

Claims 18 and dependent claims 21-25 stand rejected for lack of enablement. The examiner maintains that "[t]he claims are broad in that they indicated "pretreatment" but do not define the same in the claim." *Office Action Mailed May 9, 2005* at 2. While the examiner agrees that the specification is enabling, he states that the specification is enabling only for the disclosed process of pre-treating the ascorbic acid. According to the examiner, a topical composition comprising ascorbic acid pretreated by other processes is not enabled. *Id.*

Enablement is determined by whether undue experimentation is needed to practice the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Whether experimentation is undue is based on consideration of the following factors: breadth of the claims, nature of the invention, state of the prior art, level of one of ordinary skill, level of predictability in the art, amount of direction provided by the inventor, existence of working

examples, quantity of experimentation needed to make or use the invention based on the content of the disclosure. *Id.* It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. *Id.*

One skilled in the art can practice the claimed composition without undue experimentation. The specification clearly defines each of the constituents of the topical composition of Claim 18. *Application* at 5, ls. 8-17. The specification also teaches that pretreatment of the ascorbic acid provides additional efficacy, storage stability and lowering of skin irritability. *Id.* at 5, ls. 3-8; p. 6, ls. 30-32; and p. 7, ls. 27 to 30. Pretreatment of ascorbic acid is taught by example as "ascorbic acid which has been dissolved in water at a relatively high temperature forms a concentrated ascorbic acid solution." *Id.* at 6, line 32 to 7, line 2. The temperatures for dissolving the acid in water are taught as 60 to 90 °C. *Id.* No experimentation is needed to make the claimed composition based on teaching of the specification.

The enablement requirement of 35 U.S.C. § 112 is satisfied provided a specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The topical composition of claim 18 not only has pretreated ascorbic acid, but also contains at least 5.0% (w/v) ascorbic acid, water, and a non-toxic zinc salt. The composition must also have a pH from 3.5 to 4.1. The scope of the claim 18 is not any topical composition containing pretreated ascorbic acid. Rather, the scope of claim 18 is also limited to the constituents and pH claimed therein.

The specification of the subject application discloses at least one method of making and using the claimed topical composition that bears a reasonable correlation to the scope of claim

18. *Id.* at 4, l. 31 to p. 5, l. 2; p. 6, l. 32 to p.7, l.8. Specifically, the specification teaches how to make and use the composition. *Id.* at 10, ls. 15-25; p. 6, ls. 32 to p. 7, l. 8 and p. 11, ls. 4-29. As mentioned above, pretreatment of ascorbic acid is taught in the specification at page 4, line 31 through page 5, line 2, and at page 6, line 32 through page 7, line 8. Pretreatment is further taught by example at page 7, lines. 27 through 31. When the ascorbic acid is pretreated, the topical composition of the subject invention has additional benefits in that it does not expand, explode, or discolor as a result of heat, changes in atmospheric pressure, or improper storage. *Id.* at 5, ls. 3-8.

Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. § 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987). Alternative methods of ascorbic acid pretreatment are known to those skilled in the art. For example, U.S. Pat. No. 6,103,267 teaches a pretreatment of ascorbic acid by first mixing it with water-soluble polymer and water. The pretreated ascorbic acid is then mixed with a surface agent to form a dispersion mixture useful in cosmetics. Notwithstanding the teachings of pretreatment in the prior art, the prior art methods of pretreatment are not taught or suggested in combination with the constituents that make up the topical composition of the present invention. With or without pretreatment of the ascorbic acid, the topical composition of the subject invention is not taught or suggested by the prior art.

In summary, the breadth of the claim 18, the nature of the invention, the amount of direction provided by the inventor, the existence of a working example, the quantity of experimentation needed to make or use the invention based on the content of the disclosure

clearly enables the topical composition of claim 18 - a topical composition having a particular pH and containing pretreated ascorbic acid, water and zinc. The specification enables claim 18 because one skilled in the art can practice the claimed invention without undue experimentation.

## II. Rejection of the Claims under 35 U.S.C. § 112, second paragraph, as Incomplete for Omitting Essential Elements is Improper.

Claims 18 and 21-25 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements and that the omission amounts to a gap between the elements. *Office Action* Mailed May 9, 2005 at 3. According to the examiner, the omitted elements are the process steps by which the ascorbic acid is pretreated as the pretreatment process "appears to be critical to the invention and should be included in the claims." *Id.*

Section 112, second paragraph of the Patent Act states: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, second paragraph, contains two requirements, 1) the claims must be directed to the subject matter that the applicant regards as his or her invention and 2) precision and definiteness. *See, e.g.,* MPEP 2171. If the scope of subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that he intends that claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention." *In re Borkowski*, 422 F.2d 904, 909, 164 USPQ 642, 645-46 (CCPA 1970).

Therefore, a rejection under section 112, second paragraph is appropriate only where applicant has stated that the invention is something different from what is defined by the claims. *In re Moore*, 439 F.2d 1232, 1235, 169 U.S.P.Q. 236, 238 (CCPA 1971); *See also,* MPEP 2172.

In the absence of evidence to the contrary, the invention set forth in the claims must be presumed to be that which applicants regard as their invention. *Id.*

Furthermore, the content of applicant's specification cannot be used as evidence that the scope of the claims is inconsistent with the subject matter regarded as the invention by applicants. As noted in *In re Ehrreich*, agreement between the claims and the specification, or lack thereof, is properly considered only with respect to section 112, first paragraph and is irrelevant to compliance with the second paragraph of this section. *In re Ehrreich*, 590 F.2d 902, 906, 200 USPQ 504, 508 (CCPA 1979).

Applicant has never defined or discussed its invention as something other than what is defined by the claims. The invention set forth in the claims must be presumed to be that which applicant regards as her invention. *In re Moore*, 439 F.2d at 1235. In light of the forgoing, the rejection under section 112 second paragraph for unclaimed subject matter is improper.

### III. Rejection of the Claims 1, 3-8, 10-12, 15-18, 21, 23-25 under 35 U.S.C. § 103 (a) as Unpatentable Over Schinitsky in view Murad, Herstein and Bassford is Improper.

Claims 1, 3-8, 10-12, 15-18, 21, 23-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Schinitsky, et al.*, U.S. Pat. No. 4,938,969, in view of *Murad*, U.S. Pat. No. 5,804,594, *Herstein,* U.S. Pat. No. 5,902,591, and *Bassford et al,* U.S. Pat. No. 2,517,276. The examiner maintains that the claimed invention, as a whole, would have been prima facie obvious because "every element of the invention has been collectively taught by the combined teachings of the references." *Office Action Mailed May 9, 2005* at 4. He supports this conclusion by going through the cited prior art references one by one in order to identify one or more elements of the present invention.

However, in his nine page office action and over the three years of patent prosecution, the examiner has not identified a single teaching or suggestion in the prior art that motivates his combination of references, or suggests a modification of the teaching of *Schinitsky, et al.* in order to arrive at the present invention. As the examiner picks through the prior art to find and match up the elements of the claimed invention, it is only through hindsight motivation that the examiner arrives at the present invention through his combination of references. The examiner has failed to meet his burden of prima facie obviousness because *Schinitsky, et al.* cannot be properly modified or combined with one or more of the other references for lack of the requisite motivation and suggestion.

The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence. The factual evidence derives from an inquiry into the scope and content of the prior art, the differences between the prior art and the claimed subject matter and the level of ordinary skill in the art at the time the invention was created. *Ruiz v. A.B. Chance Co.,* 234 F.3d 654, 57 U.S. P.Q. 2d 1161 (Fed. Cir. 2000).

The examiner agrees that there are differences between the prior art and the claimed invention in that "the prior art does not expressly disclose the combination of at least 10% [5%], non-toxic zinc salt, water and pH of 3.5 to 4.1." *Office Action Mailed May 9, 2005* at 6. Notwithstanding, he maintains that the prior art amply suggests the combination because the prior art discloses: (a) the combination of ascorbic acid and zinc; (b) the use of ascorbic acid up to 20 percent; (c) dissolving ascorbic acid in water at 60 degrees Celsius; and (d) that a pH of 3.5 to 4.1 is preferred to facilitate entry of the acid into the skin. *Id.* However, the prior art fails to

teach, suggest, or motivate the combination of references proposed by examiner in order to arrive at the claimed invention.

*Schinitsky, et al.* teach a composition for reducing the depth or intensity of fine wrinkles in skin affected by intrinsic or photo induced aging. The topical composition of *Schinitsky, et al.* requires tyrosine, ascorbic acid and zinc salt. *Schinitsky, et al.* teach that its topical composition is better than the popular tretinoin compositions because tretinon only stimulates epidermal cells, but does not result in any observable changes in dermis. *U.S. Pat. No. 4,938,969,* at Col. 2, ls. 25-29. *Schinitsky, et al.* teach that a combination of tyrosine (an amino acid), ascorbic acid and a non-toxic zinc salt when applied to areas showing fine wrinkles (associated with sun or aging) results in a readily perceivable dimunition of the fine wrinkle structure. *Id.* at Col. 2, ls. 5-17.

Furthermore, *Schinitsky, et al.* teach that: "[w]hile the mode of action of the present composition is not wholly understood, it is believed that **the ingredients cooperate to stimulate** fibroblast proliferation and **to promote** their production of collagen and elastin." *Id.* at Col. 2, ls. 11-16. *emphasis added.* Even though *Schinitsky, et al.* identify zinc sulfate as an essential ingredient in their topical composition, *Schinitsky, et al.* also teach zinc salt must be combined with tyrosine in a pharmaceutically acceptable vehicle to have such effect. *Id.* at Col. 3, l. 7-Col. 4, l. 32. In the preliminary (double-blind) trial and after 50 subjects had used one or both creams (with and without tyrosine), the code identifying the test cream (with tyrosine and ascorbic acid) and control cream (without tyrosine and ascorbic acid) was broken. Of those 50 patients using the test cream (with tyrosine), 48 out of 50 subjects had noted "improvement with the test cream in either the first or second week [of a] four week test period." *Id.* at Col. 4, ls. 19-22. No improvement was noted for the control cream, without tyrosine.

*Schinitsky, et al.* only teach the combination of tyrosine, ascorbic acid and zinc sulfate to diminish wrinkles. *Schinitsky, et al.* do not teach or suggest that zinc salt alone or in combination with absorbic acid without tyrosine. Nor do *Schinitsky, et al.* suggest a pH for any topical composition. For this, the examiner picks out *Herstein* U.S. Pat. No. 5,902,591.

*Herstein* teaches a two-component system of a powdered ascorbic acid phase and a liquid phase, the liquid phase containing an emulsion having an effective amount of an organoclay material to stabilize the emulsion. Having an organoclay to stabilize it, the pH of the overall component system of *Herstein* is 3.5 to 4.1. While *Herstein* recommends between about 0.1% to about 20% by weight of ascorbic acid in its powder phase, *Herstein* does not teach or suggest a topical composition comprising ascorbic acid, water and zinc salt.

Furthermore, in distinguishing his two-component system from the prior art, *Herstein* points to U.S. Pat. No. 2,400,171 that discloses preparations preferably maintained at a pH of 7 to 7.3 and containing metal ascorbates (such as a zinc salt of ascorbic acid). These prior art preparations identified by *Herstein* contain added stabilizers whereas the teaching of *Herstein* is directed to the use of a new stabilizer, and not combinations of ascorbic acid, water and zinc salt. *See e.g., U.S. Pat. No. 2,400,171* at Col. 3, ls. 23-30

Most importantly, there is no motivation or suggestion (or reason) provided by *Schinitsky, et al.* or *Herstein* to combine the teaching of the other and arrive at the claimed topical composition. *Herstein* does not suggest using tyrosine in its topical composition. Moreover, neither *Schinitsky, et al.* nor *Herstein* suggest the use of zinc salt either alone or in combination with ascorbic acid to produce a stable topical composition. Rather, *Herstein* teaches the use of an organoclay to stabilize a two-component system. The motivation to

combine these references is provided only through the teaching of the specification of the present invention.

Furthermore, *Murad*, U.S. Pat. No. 5,809,594 is directed to a compositions containing a sugar compounds. In *Murad*, ascorbic acid must be used in combination with amino acids and sugar. Also, the transition metal (such as zinc) is preferably complexed with an amino acid. According to *Murad*, the "zinc component may be any zinc compound or pharmaceutically acceptable salt thereof, **but more preferably is a zinc complexed with an amino acid, and most preferably is zinc monomethionine**, wherein the zinc is typically present in about 10 to 30 weight percent of the complex." *U.S. Pat. No. 5,804,594* at Col. 6, ls. 44-48. In contrast to *Schinitsky, et al.*, *Murad's* composition preferably has "at least two amino acids selected from the group of proline, lysine, cysteine, and methionine are present, and at least two the transition metal components including zinc, manganese or copper, or mixtures thereof." *Id.* at Col. 3, ls. 45-51. Unlike *Herstein*, Murad does not teach or suggest a two-component system or unique stabilizer. Moreover, all of the examples provided by *Murad* are oral formulations, not topical compositions.

*Murad* does not teach or suggest ascorbic acid be combined with a zinc salt and water to produce a topical composition. *Murad* does not teach or suggest that any of one or more of these components be separately combined to produce a useful topical composition, or a topical composition having a pH between 3.5 and 4.1. Furthermore, there is no teaching or suggestion in *Schinitsky, et al, Murad* and/or *Herstein* to combine these references in order to arrive at the claimed invention. The motivation for doing so can only be found through the teaching of the present invention.

The Examiner states that "one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the same would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid according to the processing in Bassford with the expectation that the product would sufficiently pure for pharmaceutical purposes." *Id.*

Keeping in mind Claim 18 is further limited to pretreated ascorbic acid, the Examiner states "*Bassford et al.* disclose a method of purifying ascorbic acid in which one of the steps includes dissolving ascorbic acid in distilled water at 60 degrees Celsius..." *Office Action Mailed May 9, 2005* at 5. *Bassford et al.,* however, does not teach, disclose or suggest a topical composition, a composition containing a zinc salt, or a composition at a particular pH. *Bassford et al.* only teaches how to get the ascorbic acid into a purified form that is good enough for a pharmaceutical composition. There is no motivation or suggestion offered by *Bassford et al.,* to combine its purification method with the teachings of *Schinitsky, et al., Murad* and/or *Herstein* to arrive at the topical composition as defined by Claim 18.

Because of the requisite lack of motivation and/or suggestion to modify the composition of *Schinitsky, et al.* (tyrosine, ascorbic acid and zinc salt) by combination of the teachings of *Murad, Herstein* and/or *Bassford et al.*, the examiner has failed to make a prima facie case of obviousness of the claimed invention. The examiner has not met (and cannot meet) his burden. Therefore, the rejection is improper and must be withdrawn.

## IV. Rejection of the Claims 1, 3-8, 10-12, 15-18, 21, 23-25 under 35 U.S.C. § 103 (a) as being Unpatentable Over Schinitsky in view Murad, Darr and Bassford is Improper.

Claims 1, 3-8, 10-12, 15-18, 21, 23-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Schinitsky, et al.,* U.S. Patent No. 4,938,969, in view of *Murad,* U.S. Patent No. 5,804,594, *Darr et al.,* U.S. Patent No. 5,140,043 and *Bassford et al.* U.S. Patent No. 2,517,276. The examiner maintains that "[t]he difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, aminosugar, water and pH of 3.5 to 4.1. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and glucosamine, the use of ascorbic acid up to 20% and that a pH of 3.5 and that at pHs of 4.2 and 4.5, a 5% solution of ascorbic acid remained stable." *See Office Action Mailed May 9, 2005,* at 10.

First, the claimed compositions comprise at least 5% w/v ascorbic acid, water, a non-toxic zinc salt and are maintained at a pH between 3.5 and 4.1. Second, *Darr et al.* do not teach or suggest a composition having a zinc salt. Third, *Darr et al.* do not teach or suggest pretreatment of ascorbic acid. Indeed, *Darr et al.* teach away from high quantities of ascorbic acid and pH above 3.5.

Specifically, *Darr et al.* teach that "...the pH of the composition is no more than about 3 to 3.5, preferably no more that about 2.5." *See U.S. Pat. No. 5,140,043* at Col. 3, ls. 29-32 *Darr* also teaches that his invention relates "topical compositions containing L-ascorbic acid (vitamin C) which are stabilized in aqueous solutions by providing a concentration of L-ascorbic acid above about 1% (w/v) and maintaining the pH below about 3.5." *Id.* at Col. 1, ls. 9 to 11. As described, the composition of *Darr et al.* is not stable at a pH of up to 4.5. Furthermore, *Darr et*

*al.* presents data demonstrating a decrease in the amount of ascorbic acid over time at a pH above 4.2. *Id.* at Figure 3. Similarly, the data also demonstrates that there is spectral broadening of the ascorbic acid over time at pH above 4.2. *Id.* at Figures 4 and 5.

There is no teaching or suggestion in the prior art references to combine the teaching of *Darr et al.* (a composition without a zinc salt) with the compounds found in *Schinitsky et al., and Murad* together with the purification of ascorbic acid of *Bassford et al.* and arrive at the claimed invention. Here again, the examiner has not met his burden of prima facie obviousness for lack of the requisite motivation to combine.

To establish a prima facie case of obviousness, there must be a motivation or suggestion to combine the references. The examiner has not pointed to the motivation (or suggestion) as provided by the prior art to combine the teachings of *Schinitsky et al.* and *Murad*, and/or *Darr et al.* together with *Bassford et al.* and arrive at the claimed invention. While the motivation to combine may be found in the prior art references, knowledge of those of skill in the art or from the nature of the problem to be solved, the examiner has not pointed to a single teaching in any of the references that would motivate or suggest the combination. He has not because he cannot. Therefore, the examiner has not met his burden. Hence, this rejection must be withdrawn.

**Summary**

Appellant respectfully submits that the claimed compositions are enabled by the specification and can be practiced without undue experimentation. Appellant further submits that the examiner has not met his burden under 35 U.S.C. § 103 in making a prima facie case of obviousness.

For all of the foregoing reasons, the rejections of claims are improper and the basis for the rejections erroneous. Reversal of the examiner's rejections is respectfully requested.

Respectfully submitted,

Date: January 5, 2006

By: Carol M. Nielsen

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## CLAIMS APPENDIX

Claim 1. A topical composition comprising:

at least about 5.0% (w/v) ascorbic acid;

non-toxic zinc salt; and

water, wherein the composition has a pH of 3.5 to 4.1.

Claim 3. The composition of claim 1, wherein the composition has a pH of about 3.7 to about 4.0.

Claim 4. The composition of claim 1, further comprising an anti-inflammatory compound.

Claim 5. The composition of claim 4, wherein the anti-inflammatory compound includes sulfur-containing anti-inflammatory compound.

Claim 6. The composition of claim 5, wherein the sulfur-containing anti-inflammatory compound is selected from the group consisting of cystine, cysteine, N-acetyl cysteine, glutathione, cysteamine, S-methylcysteine, methionine and mixtures thereof.

Claim 7. The composition of claim 4, wherein the anti-inflammatory compound includes aminosugar.

Claim 8. The composition of claim 7, wherein the aminosugar includes glucosamine, mannosamine, N-acetylmannosamine, galactosamine, glucosamine-6-phosphate, N-acetylglucosamine, N-acetylmannosamine, N-acetylgalactosamine and mixtures thereof.

Claim 10. The composition of claim 1, wherein the water is selected from the group consisting of distilled water, deionized water, distilled deionized water and mixtures thereof.

Claim 11. The composition of claim 1, wherein the non-toxic zinc salt is present in an amount ranging from about 0.5% to about 5% (w/v).

Claim 12. The composition of claim 11, wherein the non-toxic zinc salt is zinc sulfate.

Claim 15. The composition of claim 1, further comprising a pharmaceutically acceptable carrier.

Claim 16. The composition of claim 15, wherein the pharmaceutically acceptable carrier includes glycerol, propylene glycol, sorbitol, hydroxypropylcellulose or a mixture thereof.

Claim 17. The composition of claim 15, wherein the pharmaceutically acceptable carrier includes alkyleneglycol, hydroxyalkylcellulose or a mixture thereof.

Claim 18. A topical composition comprising:

an aqueous solution including at least about 5.0% (w/v) pre-treated ascorbic acid, a non-toxic zinc salt, and having a pH of 3.5 to 4.1.

Claim 21. The composition of claim 18, further comprising a stimulant of protein synthesis.

Claim 23. The composition of claim 18, further comprising a precursor of melanin synthesis.

Claim 24. The composition of claim 18, comprising about 15% to about 25% (w/v) ascorbic acid.

Claim 25. The composition of claim 18, wherein the topical composition is an aqueous solution, a serum, a lotion, an ointment, a cream, or a gel.

## EVIDENCE APPENDIX

None.

## RELATED PROCEEDINGS APPENDIX

None.